RNK Products, Inc.

K072026

OCT 26 2007

510(k) SUMMARY
RNK Products, Inc.
Electronic Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K

Submitter Information

Submitter:	RNK Products, Inc. 12700 Diamond Drive Burnsville, MN 55337 Telephone: (612) 414-0289 Facsimile: (952) 894-2623
Contact Person:	Charles R. Abbruscato
Date Prepared:	July 16, 2007

Device Information

Name of Device	RNK Electronic Stethoscope
Common or Usual Name	Electronic Stethoscope
Classification Name	Electronic Stethoscope
Predicate Devices	RNK Products TR-1 (K030446) and Meditron Stethoscope (K991367)

Device Description

The RNK Electronic Stethoscope is comprised of a Chest Piece assembly, an Amplifier module containing an amplifier, and a standard audio Headset. The Chest Piece assembly and Headset are detachable and can plug into the Amplifier module. The Amplifier module amplifies and filters the signal from the Chest Piece and presents it to the attached Headset.

A standard 3.5 mm audio cable is used to connect the RNK Chest Piece Assembly to the RNK Amplifier. A standard, off-the-shelf Headset with a 3.5 mm plug can plug into the RNK Amplifier to enable a listener to hear the sounds from the RNK Chest Piece.

The RNK Amplifier is powered by x2 AAA batteries, which can be easily accessed for replacement. Unplugging the RNK Chest Piece puts the Amplifier into low power mode.

The RNK Electronic Stethoscope provides up to about 20 times greater amplitude signal than a typical acoustic stethoscope. The overall auscultation frequency response of the RNK Electronic Stethoscope is 20 Hz – 1,500 Hz.

Intended Use

The RNK Electronic Stethoscope is intended for use in detecting and amplifying heart, lung and other body sounds for diagnostic or monitoring purposes on any patient undergoing a physical assessment.

Substantial Equivalence

The RNK Electronic Stethoscope is substantially equivalent to the RNK Products TR-1 (K030446) and the Meditron Stethoscope (K991367). The effectiveness of the RNK Electronic Stethoscope has been demonstrated in user testing with clinicians.

The RNK Electronic Stethoscope has the same intended use, principles of operation and technological characteristics as the auscultation function of the predicate devices. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2007

RNK Products, Inc.
c/o Mr. Charles R. Abbruscato
CEO
12700 Diamond Drive
Burnsville, MN 55337

Re: K072026
Trade Name: RNK Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: October 15, 2007
Received: October 16, 2007

Dear Mr. Abbruscato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072026

Device Name: RNK Electronic Stethoscope

Indications for Use:

The RNK Electronic Stethoscope is intended for use in detecting and amplifying heart, lung and other body sounds for diagnostic or monitoring purposes on any patient undergoing a physical assessment.

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072026

Prescription Use: X OR Over-the-Counter Use _____
(Per CRF 801.109)

(Optional Format 1-2-96)